**Guideline and Flow Chart When University of Rochester Relies on a Non-UR IRB**

The University of Rochester (UR) may defer review of human subject research to a non-UR IRB (e.g., independent IRB or another institution’s IRB) when the research involves more than one site or the study is funded by the National Institutes of Health, as per OHSP Policy 504 RSRB Reliance for Review. When this occurs, UR becomes the Relying institution.

When the UR is the Relying institution, the UR Investigator is responsible for ensuring all appropriate agreements are in place and an institutional review is conducted according to Policy 504 RSRB Reliance for Review. The UR PI should first contact the RSRB Reliance Specialist to request that the UR defer to a non-UR IRB for review. If the request is granted, continue with the steps outlined on the UR Relying IRB Flow Chart (next page).

When the RSRB defers to a non-AAHRPP accredited IRB, the RSRB may assess whether the policies and procedures of the Reviewing IRB are consistent with the accreditation standards. The RSRB may obtain an assurance or request a self-evaluation from the Reviewing IRB (i.e. AAHRPP’s Evaluation Instrument for Accreditation, FDA’s self-evaluation checklist for IRBs), or another satisfactory process.

As part of this process, the RSRB will conduct an institutional review to ensure compliance with institutional policies, such as; human subject training requirements, compensation for injury, and conflict of interest. Consent documents must include the information outlined in the University of Rochester as Relying Institution Consent Language Requirements. Please consult with the RSRB if there are any questions with the standard language when negotiating with the sponsor or reviewing institution.

*See the UR Relying IRB Flow Chart on the next page for the steps to obtain a Reliance Agreement and submit an External IRB application.*
UR Relying IRB Flow Chart

New study
UR is NOT the Reviewing IRB

Does UR have an existing Reliance Agreement with the Reviewing Institution or independent IRB?

YES
Submit an External IRB application in Click. Under the Basic Information section, question 6=Yes. Under the External IRB section select the Reviewing institution from the drop down menu. Complete the remainder of the application. On the Local Site Documents section, provide information specific to the local site (e.g., local site consent form and recruitment materials). Once the study application record is complete, the PI (or PI Proxy) submits the site for review.

RSRB reviews the application and either completes review or sends application back to the UR PI for clarification or requested edits.

NO
Contact the RSRB Reliance Specialist

Is Reviewing IRB participating in SMART IRB?

YES
Contact lead PI to initiate SMART IRB process. During the process, the Institutional profile is provided to the Reviewing IRB.

Reliance is determined. UR PI receives SMART IRB determination letter designating UR as the Relying IRB.

Reliance Agreement executed

NO
Reliance Specialist works with the Reviewing IRB to execute a Reliance agreement. During the process, the Institutional profile is provided to the Reviewing IRB.

RSRB reviews the application and either completes review or sends application back to the UR PI for clarification or requested edits.

UR PI receives letter from Reliance Specialist documenting institutional review. UR PI provides to Reviewing IRB as appropriate. Once study is reviewed and approved by the reviewing IRB, upload the approval letter and stamped consent(s) to complete the Click application.